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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,562	01/26/2001	William J. Curatolo	PC9674AJTJ	8513

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PATENT DEPARTMENT
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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
07/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	09/770,562	CURATOLO ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,23,28-38,49-51 and 53-56* is/are pending in the application.

4a) Of the above claim(s) *28-35 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,23,36,37,49-51 and 53-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of request for continued examination under 37 CFR 1.114, change of address/power of attorney, amendment and remarks, all filed 04/16/09. Claims 15, 17, 22 and 26 are canceled. Claims 1, 36, 37, 49-51, 53-56 are amended. Claims 1, 4, 23, 28-38, 49-51 and 53-56 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/16/09 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 4, 23, 36, 37, 49-51 and 53-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

4. The original specification does not envision a composition of matter that consists only of HPMCAS, sparingly soluble drug according to lines 3 and 4 of claim 1. Correction is respectfully requested.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1, 4, 49 and 53-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyajima et al. (EP 0 344 603).

7. Miyajima describes formulating NZ-105, a dihydropyridine phosphonic acid derivative, drug that is poorly soluble in water (abstract; page 2, lines 14-35; page 3, lines 6-9), by dissolving NZ-105 and HPMCAS in an organic solvent and removing the solvent by vacuum drying, spray drying or freeze drying to yield compositions that are remarkably enhanced bioavailability (page 3, lines 16-20; page 4, lines 56-58) with solid dispersions resulting from spray-drying. 1-7 parts by weight of HPMCAS are used per 1 part by weight of NZ-105. For claim 1, parts (a) and (b) are the properties of the dosage form. Claim 1 recites spray dried dispersion which in claim 4 is amorphous when undispersed and the recitation in claim 4 is also

directed to the properties of the dosage form. Claims 49, 53 and 54 recite the properties of the composition so that the composition of Miyajima meets the claims.

8. Claims 1, 4, 15, 17, 22, 49 and 53-55 are rejected under 35 U.S.C. 102(a) as being anticipated by Kigoshi et al. (EP 0 784 974).

9. Kigoshi describes solid dispersions containing xanthine derivatives and polymer (title; abstract; page 2, lines 21, 22, 44, 45); the xanthine derivatives are slightly soluble in water meeting the sparingly water soluble drug of the claims; the polymer can be a cellulose derivative (page 3, line 58) and hydroxypropylmethyl cellulose acetate succinate (HPMCAS) is one the derivatives named (page 4, line 8) meeting the requirements of the claims. One of the processes of removing the solvent for the formation of the solid dispersion is by spray-dry granulator (page 4, line 38) and the resulting granules/particles are isolated (page 4, lines 49, 50). The ratio of the xanthine derivative compound I to the polymer ranges from 3:1 to 1:5 (page 4, lines 12, 13) with the ratio of 1:5 intersecting points within the recited ratio of from 1:0.4 to 1:20 of the claims with the disclosed ratio meeting the requirements of claims 1 and 55. Claim 1 recites spray dried dispersion which in claim 4 is amorphous when undispersed and the recitation in claim 4 is also directed to the properties of the dosage form. Claims 49, 53 and 54 recite the properties of the composition so that the composition of Kigoshi meets the claims.

Response to Arguments

10. Applicant's arguments filed 04/16/09 have been fully considered but they are not persuasive.

11. Applicant states the final rejection should be withdrawn because, the submission of 11/3/2008 did not amend the claims. The finality of the office action of 02/06/2009 is

withdrawn with the filing of RCE. However, the finality was not due to claim amendment but was due to the IDS filed. Please see paragraph 15 of the final rejection of 02/06/09 and also MPEP 609.04(b).

12. Applicant's argument that Miyajima and Kigoshi failed teach or suggest any process of making solid amorphous dispersion of low-solubility drug with HPMCAS using no other components other than drug, HPMCAS and solvent is not persuasive because the claims are not directed to process of making dispersions but to compositions comprising solid dispersions. The comprising language in line 1 of the claim is open.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 23, 36, 37, 49-51 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obara et al. ("Influence of processing variables on the properties of free films prepared from aqueous polymeric dispersions by a spray technique," in International Journal of Pharmaceutics 126 (1995) 1-10) in view of Akiyama et al. (US 5,576,025).

Obara discloses that pharmaceutical dosage forms spray dried dispersions using hydroxypropylmethyl cellulose acetate succinate (AQOAT = HPMCAS) produced particles with a mean particle size of 5 μm (abstract, para. 1). Obara does not mention any specific drugs.

But poorly water soluble antipsychotic drugs are known to be formulated into coated granules by spray coating with polymers such as HPMCAS (Akiyama at column 6, lines 14 and 26; column 9, line 13; column 11, line 60; column 12, line 52; column 13, lines 39-44).

Claim 1 recites spray dried dispersion which in claim 4 is amorphous when undispersed and the recitation in claim 4 is also directed to the properties of the dosage form. Regarding claim 50, the prior art does not say that the product is free of any solvent. Because both the drugs of the prior art and the claimed invention are poorly water soluble, and the drugs such as chlorpromazine disclosed in the prior art meets the requirements of claim 36, then the solubility parameter recited in claim 53 would be inherent to the dose of the prior art. Regarding claim 37, since the prior art spray coats antipsychotic drug with HPMCAS, it would be reasonably expected that another antipsychotic drug such as claimed in claim 37 would also be successfully coated. However, the prior art does not teach the ratio of the drug to polymer. But, taking the generic teachings of the prior art, one having ordinary skill in the art at the time the invention was made would have good reason to use specific amounts drug and polymer in a defined drug/polymer ration that would lead to the anticipated success of spray coated/dried dosage forms.

Response to Arguments

14. Applicant directs the examiner's attention to the arguments filed 11/10/08. The examiner fully responded to applicant's arguments filed 11/10/08 and is also noted that the remarks were filed 11/10/08 and not 11/3/08; the response to the arguments filed 11/10/08 is provided in paragraphs 7-10 of the office action of 02/06/09.

15. Applicant's arguments filed 04/16/09 have been fully considered but they are not persuasive.

16. Applicant argues that the amended claims are not open to the inclusion of the viscogenic coating agent of Akiyama matrix. The examiner disagrees because the comprising language of the claims in line 1 of claim 1 is open.

17.

18. Claims 1, 23, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyajima et al. (EP 0 344 603) or Kigoshi et al. (EP 0 784 974).

19. Miyajima: Miyajima is described above as anticipating claim 1. For claims 50 and 51, since the formulation of Miyajima and that of the instant claims are spray dried, it would be reasonable to expect that the residual solvent in the formulation of Miyajima and the composition of the claims would be the same except there is factual evidence that it's not. Although, Miyajima's spray dried formulations are granules, Miyajima does not specifically teach the particle size of claim 23. However, a person of ordinary skill in the art has the ordinary capabilities to determine the size of the resultant granules/particles. In the absence of factual evidence, particles having sizes of less than 100 μm are not inventive over the granules/particles of Miyajima.

20. Kigoshi: Kigoshi has been described above as anticipating claim 1. For claims 50 and 51, since the formulation of Kigoshi and that of the instant claims are spray dried, it would be reasonable to expect that the residual solvent in the formulation of Kigoshi and the composition of the claims would be the same except there is factual evidence that it's not. Although, Kigoshi's spray dried formulations are granules, Kigoshi does not specifically teach the particle

size of claim 23. However, a person of ordinary skill in the art has the ordinary capabilities to determine the size of the resultant granules/particles. In the absence of factual evidence, particles having sizes of less than 100 μm are not inventive over the granules/particles of Kigoshi.

21. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Blessing M. Fubara/
Examiner, Art Unit 1618